

**IN THE UNITED STATES DISTRICT COURT
FOR THE EASTERN DISTRICT OF PENNSYLVANIA**

| | | |
|---------------------|---|------------------------|
| DOROTHY J. SWISHER, |) | |
| |) | |
| Plaintiff, |) | |
| |) | |
| v. |) | Civil Action No: _____ |
| |) | |
| MONSANTO COMPANY, |) | |
| |) | |
| Defendant. |) | |
| _____ |) | |

MONSANTO COMPANY’S ANSWER TO PLAINTIFF’S COMPLAINT

Pursuant to Rule 12 of the Federal Rules of Civil Procedure, Defendant Monsanto Company (“Monsanto”), by and through its counsel, respectfully responds by generally denying all allegations contained in plaintiff Dorothy J. Swisher’s Complaint and Jury Demand (“the Complaint”), except as set forth below. As defined in the Complaint and as used in this Answer, Monsanto refers to Monsanto Company, a United States based company incorporated in Delaware, and not to other Monsanto-affiliated companies. Silence as to any allegations shall constitute a denial.

1. Monsanto admits that plaintiff purports to bring an action for damages allegedly related to exposure to Roundup[®]-branded products but denies any liability to plaintiff. Monsanto denies the remaining allegations in paragraph 1.

2. Monsanto denies the allegations in paragraph 2.

3. Monsanto denies the allegations in paragraph 3.

4. Monsanto denies the allegations in in paragraph 4.

5. The allegations in the first sentence of paragraph 5, including footnote 1, set forth conclusions of law for which no response is required. Monsanto admits the allegations in the

second sentence of paragraph 5.

6. The allegations in paragraph 6 set forth conclusions of law for which no response is required.

7. Monsanto denies the allegations in the first sentence of paragraph 7. In response to the second sentence of paragraph 7, Monsanto admits that it sells Roundup®-branded products in Pennsylvania.

8. Monsanto denies the allegations in paragraph 8.

9. Monsanto lacks information or knowledge sufficient to form a belief as to the truth of the allegations in the first sentence of paragraph 9 and therefore denies those allegations. Monsanto denies the remaining allegations in paragraph 9.

10. The allegations in paragraph 10 comprise attorney characterizations and are accordingly denied. Monsanto states that the Roundup®-branded products identified by plaintiff have a variety of separate and distinct uses and formulations.

11. Monsanto admits the allegations in paragraph 11.

12. The allegations in paragraph 12 comprise attorney characterizations and are accordingly denied.

13. In response to the allegations in paragraph 13, Monsanto admits that it sells Roundup®-branded products in Pennsylvania.

14. Monsanto lacks information or knowledge sufficient to form a belief as to the truth of the allegations in paragraph 14 and therefore denies those allegations.

15. The allegations in paragraph 15 are vague and conclusory and comprise attorney characterizations and are accordingly denied.

16. The allegations in paragraph 16 are vague and conclusory and comprise attorney characterizations and are accordingly denied.

17. Monsanto admits the allegations in paragraph 17.

18. Monsanto admits that it is authorized to do business in Pennsylvania. The remaining allegations in paragraph 18 are vague and conclusory and comprise attorney characterizations and are accordingly denied.

19. The allegations in paragraph 19 set forth conclusions of law for which no response is required.

20. Monsanto denies the allegations in paragraph 20.

21. Monsanto admits that it has designed, researched, manufactured, tested, advertised, promoted, marketed, sold, and distributed Roundup®-branded products. The remaining allegations in paragraph 21 set forth conclusions of law for which no response is required.

22. Monsanto admits that it is an agricultural biotechnology corporation with a principal place of business in St. Louis County, Missouri. Monsanto admits that it and its affiliated companies have operations and offices in countries around the world. Monsanto states that the remaining allegations in paragraph 22 are vague and that it accordingly lacks information or knowledge sufficient to form a belief as to the truth of the remaining allegations and therefore denies those allegations.

23. Monsanto admits the allegations in paragraph 23.

24. Monsanto admits the allegations in paragraph 24.

25. In response to the allegations in paragraph 25, Monsanto admits that glyphosate is an herbicide that is used to kill invasive plants and weeds. The remaining allegations in

paragraph 25 are vague and ambiguous and Monsanto lacks information or knowledge sufficient to form a belief as to the truth of the remaining allegations in paragraph 25 and therefore denies those allegations.

26. Monsanto admits that glyphosate's mode of action is targeting EPSP synthase. The remaining allegations in paragraph 26 comprise attorney characterizations and are accordingly denied.

27. Monsanto admits the allegations in paragraph 27.

28. Monsanto generally admits the allegations in paragraph 28, but denies the allegations in paragraph 28 to the extent that they suggest that glyphosate is present in any plants at anything other than *de minimis* amounts well within regulatory safety levels, as determined by the United States Environmental Protection Agency ("EPA").

29. Monsanto lacks information or knowledge sufficient to form a belief as to the truth of the allegations in paragraph 29 and therefore denies those allegations.

30. Monsanto admits that it is the leading producer of seeds that contain the Roundup Ready® trait and that use of crops with the Roundup Ready® trait substantially improve a farmer's ability to control weeds. Monsanto lacks information or knowledge sufficient to form a belief as to the accuracy of the specific numbers and statistics provided in the remaining sentences of paragraph 30 and therefore denies those allegations. Monsanto denies the remaining allegations in paragraph 30.

31. Monsanto admits the allegations in paragraph 31.

32. Monsanto admits that Roundup®-branded products have been used by farmers for approximately 40 years. Monsanto denies that Roundup®-branded products have carcinogenic properties and denies the remaining allegations in paragraph 32.

33. The allegations in paragraph 33 set forth conclusions of law for which no response is required. To the extent that a response is deemed required, Monsanto admits the allegations in paragraph 33.

34. In response to the allegations in paragraph 34, Monsanto admits that EPA requires registrants of herbicides to submit extensive data in support of the human health and environmental safety of their products and further admits that EPA will not register or approve the labeling of herbicides that do not satisfy the requirements set forth in the Federal Insecticide, Fungicide, and Rodenticide Act (“FIFRA”). The remaining allegations in paragraph 34 set forth conclusions of law for which no response is required.

35. The allegations in paragraph 35 set forth conclusions of law for which no response is required.

36. Monsanto admits that Roundup®-branded products are registered by EPA for manufacture, sale and distribution and are registered by the State of Pennsylvania for sale and distribution.

37. In response to the allegations in paragraph 37, Monsanto admits that EPA requires registrants of herbicides to submit extensive data in support of the human health and environmental safety of their products and further admits that EPA will not register or approve the labeling of herbicides that do not satisfy the requirements set forth in FIFRA. Monsanto states that the term “the product tests” in the final sentence of paragraph 37 is vague and ambiguous, and Monsanto therefore denies the same. The remaining allegations in paragraph 37 set forth conclusions of law for which no answer is required.

38. Monsanto denies the allegations in paragraph 38 to the extent that they suggest that EPA only evaluates the safety of pesticide products on the date of their initial registration.

Monsanto admits that EPA is in the process of conducting regulatory review of various pesticide products, but Monsanto lacks information or knowledge sufficient to form a belief as to the truth of the allegations in paragraph 38 regarding such pesticide products generally and therefore denies those allegations. The remaining allegations in paragraph 38 set forth conclusions of law for which no response is required.

39. In response to the allegations in paragraph 39, Monsanto admits that EPA has undertaken a regulatory review of glyphosate and further admits that EPA has not released its findings. Monsanto states, however, that: (a) in September 2016, EPA’s Office of Pesticide Programs (“OPP”) issued a 227-page evaluation of glyphosate’s carcinogenic potential, concluding that “[t]he strongest support is for [the descriptor] ‘not likely to be carcinogenic to humans’ at doses relevant to human health risk assessment”¹; and (b) at the same time, EPA posted an October 2015 final report by its standing Cancer Assessment Review Committee (“CARC”), in which CARC endorsed EPA’s existing classification of glyphosate as “Not Likely to be Carcinogenic to Humans.”² Monsanto further states that, in December 2017, EPA’s OPP issued a detailed, lengthy revised evaluation of glyphosate’s carcinogenic potential that reiterated the conclusion that “[t]he strongest support is for [the descriptor] ‘not likely to be carcinogenic to humans’.”³ Monsanto lacks information or knowledge sufficient to form a belief as to the truth of the remaining allegations in paragraph 38 and therefore denies those allegations.

¹ EPA’s Office of Pesticide Programs, *Glyphosate Issue Paper: Evaluation of Carcinogenic Potential* at 141 (Sept. 12, 2016) (“EPA OPP Report”), <https://www.regulations.gov/document?D=EPA-HQ-OPP-2016-0385-0094>. The EPA OPP Report was prepared in anticipation of an EPA Scientific Advisory Panel meeting on glyphosate’s carcinogenic potential.

² Cancer Assessment Review Committee, Health Effects Division, Office of Pesticide Programs, U.S. Environmental Protection Agency, *Cancer Assessment Document – Evaluation of the Carcinogenic Potential of Glyphosate* at 10, 77 (Final Report, Oct. 1, 2015) (“EPA CARC Final Report”), <https://www.regulations.gov/document?D=EPA-HQ-OPP-2016-0385-0014>.

³ EPA’s Office of Pesticide Programs, *Revised Glyphosate Issue Paper: Evaluation of*

40. In response to the allegations in paragraph 40, Monsanto admits that the New York Attorney General filed a lawsuit against Monsanto in 1996 alleging false and misleading advertising of Roundup®-branded products. This lawsuit was subsequently resolved without any admission of wrongdoing by Monsanto. Monsanto states that none of the New York Attorney General's allegations related in any way to a purported or alleged risk of cancer. To the extent the subparts purport to quote a document, the document speaks for itself and thus does not require any further answer. The remaining allegations in paragraph 40 are vague and conclusory and comprise attorney characterizations and are accordingly denied.

41. In response to the allegations in paragraph 41, Monsanto admits it entered into an assurance of discontinuance with the New York Attorney General. The assurance speaks for itself and thus does not require any further answer. The remaining allegations in paragraph 41 are vague and conclusory and comprise attorney characterizations and are accordingly denied.

42. Monsanto denies the allegations in paragraph 42.

43. In response to the allegations in paragraph 43, Monsanto admits that the French court ruled that Monsanto had falsely advertised its herbicide Roundup® as "biodegradable" and that it "left the soil clean," but denies the allegations in paragraph 43 to the extent that they suggest that this ruling was in any way related to plaintiff's claim here that glyphosate can cause cancer. Monsanto denies the remaining allegations in paragraph 43.

44. Monsanto denies the allegations in paragraph 44.

45. In response to the allegations in paragraph 45, Monsanto states that the cited document speaks for itself and does not require a response. To the extent that the allegations in paragraph 45 go beyond a restatement of the cited document, Monsanto lacks information or

Carcinogenic Potential at 143, 144 (Dec. 12, 2017), <https://www.regulations.gov/document?D=EPA-HQ-OPP-2016-0385-0528>.

knowledge sufficient to form a belief as to the truth of the remaining allegations in paragraph 45 and therefore denies those allegations.

46. Monsanto admits the allegations in paragraph 46.

47. In response to the allegations in paragraph 47, Monsanto states that the cited the document speaks for itself and does not require a response. To the extent that the allegations in paragraph 47 go beyond a restatement of the cited document, Monsanto lacks information or knowledge sufficient to form a belief as to the truth of the remaining allegations in paragraph 47 and therefore denies those allegations.

48. Monsanto states that the term “toxic” as used in paragraph 48 is vague and ambiguous to the extent it is intended to suggest any evidence of carcinogenicity. Monsanto denies the allegations in paragraph 48.

49. Monsanto admits the allegations in paragraph 49.

50. In response to the allegations in paragraph 50, Monsanto states that the document speaks for itself and does not require a response. To the extent that a response is deemed required, Monsanto denies the allegations in paragraph 50.

51. In response to the allegations in paragraph 51, Monsanto admits that Julie Marc published a study entitled “Glyphosate-based pesticides affect cell cycle regulation” in 2004. To the extent that paragraph 51 characterizes the meaning of the cited study, Monsanto denies the remaining allegations in paragraph 51.

52. In response to the allegations in paragraph 52, Monsanto states that these documents speak for themselves and do not require a response. To the extent that a response is deemed required, Monsanto denies the allegations in paragraph 52.

53. In response to the allegations in paragraph 53, Monsanto states that the cited document speaks for itself and does not require a response. To the extent that paragraph 53 characterizes the meaning of the cited study, Monsanto denies the remaining allegations in paragraph 53.

54. Monsanto denies the allegations in paragraph 54.

55. In response to the allegations in paragraph 55, Monsanto states that the cited document speaks for itself and does not require a response. To the extent that paragraph 55 characterizes the meaning of the cited study, Monsanto denies the remaining allegations in paragraph 55.

56. In response to the allegations in paragraph 56, Monsanto states that the cited document speaks for itself and does not require a response. To the extent that paragraph 56 characterizes the meaning of the cited study, Monsanto denies the remaining allegations in paragraph 56.

57. Monsanto denies the allegation that the cited studies support the allegation that glyphosate or Roundup®-branded products pose any risk to human health and denies the remaining allegations in paragraph 57.

58. Monsanto denies the allegations in paragraph 58.

59. Monsanto denies the allegations in paragraph 59.

60. Monsanto denies the allegations in paragraph 60.

61. Monsanto denies the allegations in paragraph 61.

62. Monsanto admits that it has in the past promoted, and continues to promote, Roundup®-branded herbicides as safe when used in accordance with the products' labeling. Monsanto denies the remaining allegations in paragraph 62.

63. Monsanto admits that the International Agency for Research on Cancer (“IARC”) is a subgroup of the World Health Organization (“WHO”) of the United Nations. Monsanto lacks information or knowledge sufficient to form a belief as to the truth of the remaining allegations in paragraph 63 and therefore denies those allegations.

64. Monsanto lacks information or knowledge sufficient to form a belief as to the truth of the allegations in paragraph 64 and therefore denies those allegations. Monsanto denies that glyphosate met the criteria necessary to be eligible for review.

65. Monsanto lacks information or knowledge sufficient to form a belief as to the truth of the allegations in paragraph 65 and therefore denies those allegations. Monsanto denies that glyphosate met the criteria necessary to be eligible for review.

66. Monsanto admits that in March 2015 IARC classified glyphosate as a class 2A carcinogen. Monsanto specifically denies that IARC’s evaluation of human, animal or genotoxic evidence was “cumulative.” The remaining allegations in paragraph 66 are vague and conclusory and comprise attorney characterizations and are accordingly denied.

67. Monsanto admits that the full IARC Monograph regarding glyphosate was published on July 29, 2015 and that the Monograph purported to classify glyphosate as a class 2A carcinogen. In response to the remaining allegations in paragraph 67, Monsanto states that the document speaks for itself and does not require a response. To the extent that a response is deemed required, the remaining allegations in paragraph 67 comprise attorney characterizations and are accordingly denied.

68. In response to the allegations in paragraph 68, Monsanto states that the document speaks for itself and does not require a response. To the extent that a response is deemed

required, the allegations in paragraph 68 comprise attorney characterizations and are accordingly denied.

69. In response to the allegations in paragraph 69, Monsanto states that the document speaks for itself and does not require a response. To the extent that a response is deemed required, the allegations in paragraph 69 comprise attorney characterizations and are accordingly denied.

70. Monsanto denies the allegations in paragraph 70.

71. The allegations in paragraph 71 comprise attorney characterizations and are accordingly denied.

72. Monsanto admits the allegations in paragraph 72.

73. In response to the allegations in paragraph 73, Monsanto states that the cited document speaks for itself and does not require a response. To the extent that paragraph 73 characterizes the meaning of the cited study, Monsanto denies the remaining allegations in paragraph 73.

74. In response to the allegations in paragraph 74, Monsanto admits that certain studies have reported that glyphosate and glyphosate-based formulations induced oxidative stress under artificial experimental conditions. Monsanto denies that these studies provide any reliable evidence that glyphosate or glyphosate-based formulations induce oxidative stress in humans or animals under real-world exposure conditions. Monsanto denies the remaining allegations in paragraph 74.

75. The allegations in paragraph 75 are vague and ambiguous and are accordingly denied.

76. In response to the allegations in paragraph 76, Monsanto states that the cited document speaks for itself and does not require a response.

77. In response to the allegations in paragraph 77, Monsanto states that the cited document speaks for itself and does not require a response. To the extent that paragraph 77 characterizes the meaning of the cited study, Monsanto denies the remaining allegations in paragraph 77.

78. Monsanto denies the allegations in paragraph 78.

79. In response to the allegations in paragraph 79, Monsanto states that the cited document speaks for itself and does not require a response. Monsanto otherwise denies the allegations in paragraph 79.

80. Monsanto admits that there is no reliable evidence that Roundup®-branded products are genotoxic, and that regulatory authorities and independent experts agree that Roundup®-branded products are not genotoxic. Monsanto otherwise denies the allegations in paragraph 80.

81. Monsanto denies the allegations in paragraph 81.

82. Monsanto denies the allegations in paragraph 82.

83. Monsanto denies the allegations in paragraph 83.

84. Monsanto admits that in 1985 EPA reviewed a regulatory study involving mice exposed to glyphosate. Monsanto denies the remaining allegations in paragraph 84.

85. Monsanto denies the allegations in paragraph 85.

86. Monsanto denies the allegations in paragraph 86.

87. Monsanto admits the allegations in paragraph 87.

88. Monsanto denies the allegations in paragraph 88.

89. Monsanto admits the allegations in paragraph 89.

90. Monsanto denies the allegations in paragraph 90.

91. Monsanto denies the allegations in paragraph 91.

92. Monsanto denies the allegations in paragraph 92.

93. Monsanto denies the allegations in paragraph 93.

94. Monsanto denies the allegations in paragraph 94.

95. Monsanto denies the allegations in paragraph 95.

96. Monsanto denies the allegations in paragraph 96.

97. In response to the allegations in paragraph 97, Monsanto admits that independent experts and regulatory agencies agree that there is no evidence of carcinogenicity or genotoxicity in glyphosate and Roundup®-branded products and admits that it has made statements reflecting this fact. Monsanto denies the remaining allegations in paragraph 97.

98. In response to the allegations in paragraph 98, Monsanto admits that Roundup®-branded products are safe, non-carcinogenic and non-genotoxic when used in accordance with the product's EPA approved labeling. Monsanto otherwise denies the allegations in paragraph 98.

99. In response to the allegations in paragraph 99, Monsanto admits that an EPA review committee classified glyphosate as Class C in 1985 based on limited data. Monsanto denies the remaining allegations in paragraph 99.

100. In response to the allegations in paragraph 100, Monsanto admits that EPA changed its classification of glyphosate to Group E based upon a full evaluation of the scientific evidence, including but not limited to three animal carcinogenicity studies. Monsanto otherwise denies the remaining allegations in paragraph 100.

101. In response to the allegations in paragraph 101, Monsanto admits that plaintiff has accurately quoted from one passage in an EPA document in 1991 with respect to the designation of an agent as Group E, but states that EPA repeatedly has concluded that glyphosate does not pose any cancer risk to humans. In addition to the conclusions in the two EPA OPP reports and the EPA CARC Final Report discussed above, other specific findings of safety include:

- “In June 1991, EPA classified glyphosate as a Group E [carcinogen]—one that shows evidence of non-carcinogenicity for humans—based on the lack of convincing evidence of carcinogenicity in adequate studies.” EPA, *Glyphosate: Reregistration Eligibility Decision (RED) Facts*, 2 (Sept. 1993), <http://archive.epa.gov/pesticides/reregistration/web/pdf/0178fact.pdf>.
- “No evidence of carcinogenicity.” Glyphosate; Pesticide Tolerances, 67 Fed. Reg. 60,934, 60,943 (Sept. 27, 2002) (to be codified at 40 C.F.R. pt. 180).
- “Glyphosate has no carcinogenic potential.” Glyphosate; Pesticide Tolerance, 69 Fed. Reg. 65,081, 65,086 (Nov. 10, 2004) (to be codified at 40 C.F.R. pt. 180).
- “There is [an] extensive database available on glyphosate, which indicate[s] that glyphosate is not mutagenic, not a carcinogen, and not a developmental or reproductive toxicant.” Glyphosate; Pesticide Tolerances, 73 Fed. Reg. 73,586, 73,589 (Dec. 3, 2008) (to be codified at 40 C.F.R. pt. 180).
- “EPA has concluded that glyphosate does not pose a cancer risk to humans.” Glyphosate; Pesticide Tolerances, 78 Fed. Reg. 25,396, 25,398 (May 1, 2013) (to be codified at 40 C.F.R. pt. 180).
- “In 2014, EPA reviewed over 55 epidemiological studies conducted on the possible cancer and non-cancer effects of [g]lyphosate. Our review concluded that this body of research does not provide evidence to show that [g]lyphosate causes cancer and does not warrant any change in EPA’s cancer classification for [g]lyphosate.” *Agriculture Biotechnology: A Look at Federal Regulation and Stakeholder Perspectives: Hearing Before the S. Comm. on Agr., Nutrition, & Forestry*, 114th Cong. (2015) (statement of Dr. William Jordan, Deputy Director of EPA’s Office of Pesticide Programs), <http://www.ag.senate.gov/templates/watch.cfm?id=74793e67-5056-a055-64af-0e55900753b4>, at time stamp 55:05-56:20 (“EPA 2015 Desk Statement”).

Monsanto denies the remaining allegations in paragraph 101.

102. In response to the allegations in paragraph 102, Monsanto admits that it – along with a large number of other companies and governmental agencies – was defrauded by two chemical testing laboratories, and that Monsanto had hired both of these laboratories to conduct

testing on glyphosate. Monsanto states that only one of these laboratories was hired to conduct toxicity tests of glyphosate. Monsanto denies that EPA's registration of glyphosate or any glyphosate-based herbicides is based upon any invalid Industrial Bio-Test ("IBT") Laboratories studies. To the extent that the allegations in paragraph 102 are intended to suggest that Monsanto was anything other than a victim of this fraud, such allegations are denied.

103. In response to the allegations in paragraph 103, Monsanto admits that IBT Laboratories was hired to conduct toxicity studies in connection with the registration of a Roundup®-branded product. Monsanto denies that EPA's regulatory approval of such product is based upon any fraudulent or false IBT studies.

104. Monsanto denies the allegations in paragraph 104 to the extent they suggest that EPA performed an inspection of IBT Laboratories solely or specifically in connection with studies conducted on glyphosate. Monsanto admits that EPA performed an audit of IBT Laboratories to investigate that laboratory's fraudulent and/or improper testing procedures in connection with services provided to a broad number of private and governmental entities and that this inspection included a review of studies IBT conducted on glyphosate. Monsanto was one of several pesticide manufacturers who had used IBT test results. The audit found some toxicology studies conducted with the original Roundup® herbicide to be invalid. As a result, Monsanto repeated all required studies in accordance with applicable EPA testing guidelines. Monsanto denies that EPA's registration of glyphosate or any glyphosate-based herbicides is based upon any invalid IBT studies. To the extent that the allegations in paragraph 104 are intended to suggest that Monsanto was anything other than a victim of this fraud, Monsanto denies those allegations.

105. In response to the allegations in paragraph 105, Monsanto admits that three IBT employees were convicted of the charge of fraud, but Monsanto denies that any of the individuals were convicted based upon studies conducted on glyphosate or glyphosate-based herbicides.

106. In response to the allegations in paragraph 106, Monsanto admits that it – along with numerous other private companies – hired Craven Laboratories as an independent laboratory to conduct residue studies for Monsanto agricultural products. Monsanto otherwise denies the remaining allegations in paragraph 106.

107. In response to the allegations in paragraph 107, Monsanto admits that EPA investigated Craven Laboratories in March 1991 for fraud. To the extent that the allegations in paragraph 107 are intended to suggest that Monsanto was anything other than a victim of this fraud, Monsanto denies those allegations.

108. In response to the allegations in paragraph 108, Monsanto admits that it was defrauded by Craven Laboratories and that, as a result, Monsanto repeated the studies conducted at Craven Laboratories at a substantial cost. To the extent that the allegations in paragraph 108 are intended to suggest that Monsanto was anything other than a victim of this fraud, Monsanto denies those allegations.

109. In response to the allegations in paragraph 109, Monsanto admits that it has stated and continues to state that Roundup®-branded products are safe when used as labeled and that they are non-carcinogenic and non-genotoxic.

110. In response to the allegations in paragraph 110, Monsanto admits that a 1986 joint report of the World Health Organization and Food and Agriculture Organization of the United Nations is cited in support of the safety of glyphosate and Roundup®-branded products.

Monsanto denies that this report is the “primary” cite in support of the safety of glyphosate and Roundup®-branded products, and denies that WHO considers glyphosate to be a probable carcinogen. Monsanto denies the remaining allegations in paragraph 110.

111. Monsanto denies the allegations in paragraph 111.

112. Monsanto denies the allegations in paragraph 112.

113. Monsanto denies the allegations in paragraph 113.

114. Monsanto denies the allegations in paragraph 114.

115. Monsanto denies the allegations in paragraph 115.

116. Monsanto denies the allegations in paragraph 116.

117. Monsanto denies the allegations in paragraph 117.

118. Monsanto denies the allegations in paragraph 118.

119. Monsanto denies the allegations in paragraph 119.

120. Monsanto denies the allegations in paragraph 120.

121. Monsanto denies the allegations in paragraph 121.

122. Monsanto lacks information or knowledge sufficient to form a belief as to the truth of the allegations in paragraph 122 and therefore denies those allegations.

123. Monsanto lacks information or knowledge sufficient to form a belief as to the truth of the allegations in paragraph 123 and therefore denies those allegations.

124. Monsanto lacks information or knowledge sufficient to form a belief as to the truth of the allegations in the first sentence of paragraph 124 and therefore denies those allegations. Monsanto denies the remaining allegations in paragraph 124.

125. Monsanto denies the allegations in paragraph 125.

126. Monsanto incorporates by reference its responses to paragraphs 1 through 125 in response to paragraph 126 of plaintiff's Complaint.

127. In response to the allegations in paragraph 127, Monsanto denies that it has concealed the alleged "true risks associated with Roundup and glyphosate." The remaining allegations in paragraph 127 set forth conclusions of law for which no response is required.

128. In response to the allegations in paragraph 128, Monsanto admits that it has stated and continues to state that Roundup®-branded products are safe when used as labeled and that they are non-toxic and non-carcinogenic.

129. In response to the allegations in paragraph 129, Monsanto states that the cited document speaks for itself and does not require a response.

130. Monsanto denies that exposure to Roundup®-branded products and glyphosate exposed plaintiff to risk of her alleged cancer and denies the remaining allegations in paragraph 130. Monsanto states, however, that the scientific studies upon which IARC purported to base its classification were all publicly available before March 2015.

131. Monsanto denies that it concealed "the true character, quality and nature of Roundup." The remaining allegations of paragraph 131 set forth conclusions of law for which no response is required. To the extent that a response is deemed required, Monsanto denies all of plaintiff's allegations in paragraph 131. Monsanto states, however, that the scientific studies upon which IARC purported to base its classification were all publicly available before March 2015.

132. Monsanto denies that it engaged in the "wrongdoing" alleged in the Complaint and denies that there is any reliable scientific evidence that exposure to glyphosate or Roundup®-branded products can cause cancer. Monsanto states, however, that the scientific studies upon

which IARC purported to base its classification were all publicly available before March 2015. The remaining allegations in paragraph 132 set forth conclusions of law for which no response is required, consist of attorney characterizations and are accordingly denied, or comprise allegations for which Monsanto lacks information or knowledge sufficient to form a belief as to the truth of the allegations asserted and therefore denies those allegations.

133. Monsanto incorporates by reference its responses to paragraphs 1 through 132 in response to paragraph 133 of plaintiff's Complaint.

134. The allegations in paragraph 134 set forth conclusions of law for which no response is required.

135. Monsanto denies the allegations in paragraph 135.

136. Monsanto denies the allegations in paragraph 136, including each of its subparts.

137. Monsanto denies the allegations in paragraph 137.

138. Monsanto denies the allegations in paragraph 138.

139. Monsanto denies the allegations in paragraph 139, including each of its subparts.

140. Monsanto denies the allegations in paragraph 140.

141. Monsanto denies the allegations in paragraph 141.

142. Monsanto denies the allegations in paragraph 142.

143. Monsanto denies the allegations in paragraph 143.

In response to the "WHEREFORE" paragraph following paragraph 143, Monsanto demands that judgment be entered in its favor and against plaintiff; that plaintiff's Complaint be dismissed, with prejudice; and that Monsanto be awarded costs of suit and reasonable attorney's fees as allowed by law and such further and additional relief as this Court may deem just and proper.

144. Monsanto incorporates by reference its responses to paragraphs 1 through 143 in response to paragraph 144 of plaintiff's Complaint.

145. In response to the allegations in paragraph 145, Monsanto lacks information or knowledge sufficient to form a belief as to the truth of the allegations that plaintiff used or was exposed to Roundup®-branded products and therefore denies those allegations. Monsanto denies the remaining allegations in paragraph 145.

146. Monsanto lacks information or knowledge sufficient to form a belief as to the truth of the allegations in paragraph 146 and therefore denies those allegations.

147. Monsanto denies the allegations in paragraph 147.

148. Monsanto denies the allegations in paragraph 148.

149. Monsanto denies the allegations in paragraph 149.

150. Monsanto denies the allegations in paragraph 150, including each of its subparts.

151. Monsanto denies the allegations in paragraph 151.

152. Monsanto denies that Roundup®-branded products have "dangerous characteristics." Monsanto lacks information or knowledge sufficient to form a belief as to the truth of the remaining allegations in paragraph 152 and therefore denies those allegations.

153. Monsanto lacks information or knowledge sufficient to form a belief as to the truth of the allegations in paragraph 153 and therefore denies those allegations.

154. Monsanto denies the allegations in paragraph 154.

155. The allegations in paragraph 155 set forth conclusions of law for which no response is required.

156. Monsanto denies the allegations in paragraph 156.

157. Monsanto denies the allegations in paragraph 157.

158. Monsanto denies the allegations in paragraph 158.

159. Monsanto denies the allegations in paragraph 159.

160. Monsanto denies the allegations in paragraph 160.

161. Monsanto denies the allegations in paragraph 161.

162. Monsanto denies the allegations in paragraph 162.

163. Monsanto denies the allegations in paragraph 163.

164. Monsanto denies the allegations in paragraph 164.

165. Monsanto denies the allegations in paragraph 165.

In response to the “WHEREFORE” paragraph following paragraph 165, Monsanto demands that judgment be entered in its favor and against plaintiff; that plaintiff’s Complaint be dismissed, with prejudice; and that Monsanto be awarded costs of suit and reasonable attorney’s fees as allowed by law and such further and additional relief as this Court may deem just and proper.

166. Monsanto incorporates by reference its responses to paragraphs 1 through 165 in response to paragraph 166 of plaintiff’s Complaint.

167. The allegations in paragraph 167 set forth conclusions of law for which no response is required.

168. Monsanto lacks information or knowledge sufficient to form a belief as to the truth of the allegations in paragraph 168 and therefore denies those allegations.

169. Monsanto denies the allegations in paragraph 169. All labeling of Roundup®-branded products has been and remains EPA-approved and in compliance with all federal requirements under FIFRA.

170. Monsanto denies the allegations in paragraph 170.

171. Monsanto denies the allegations in paragraph 171. All labeling of Roundup®-branded products has been and remains EPA-approved and in compliance with all federal requirements under FIFRA.

172. Monsanto denies the allegations in paragraph 172. All labeling of Roundup®-branded products has been and remains EPA-approved and in compliance with all federal requirements under FIFRA.

173. Monsanto denies the allegations in paragraph 173.

174. Monsanto lacks information or knowledge sufficient to form a belief as to the truth of the allegations regarding plaintiff's use history in paragraph 174 and therefore denies those allegations. Monsanto denies the remaining allegations in paragraph 174.

175. The allegations in paragraph 175 set forth conclusions of law for which no response is required.

176. Monsanto denies the allegations in paragraph 176.

177. Monsanto denies the allegations in paragraph 177.

178. Monsanto denies the allegations in paragraph 178.

179. Monsanto denies the allegations that Roundup®-branded products are defective and accordingly denies the allegations in paragraph 179.

180. The allegations in paragraph 180 set forth conclusions of law for which no response is required.

181. Monsanto lacks information or knowledge sufficient to form a belief as to the truth of the allegations in paragraph 181 and therefore denies those allegations.

182. Monsanto denies the allegations in paragraph 182.

183. Monsanto denies the allegations in paragraph 183.

184. Monsanto denies the allegations in paragraph 184.

185. Monsanto denies the allegations in paragraph 185.

186. Monsanto denies the allegations in paragraph 186.

In response to the “WHEREFORE” paragraph following paragraph 186, Monsanto demands that judgment be entered in its favor and against plaintiff; that plaintiff’s Complaint be dismissed, with prejudice; and that Monsanto be awarded costs of suit and reasonable attorney’s fees as allowed by law and such further and additional relief as this Court may deem just and proper.

187. Monsanto incorporates by reference its responses to paragraphs 1 through 186 in response to paragraph 187 of plaintiff’s Complaint.

188. Monsanto denies the allegations in paragraph 188. Additionally, the allegations in the last sentence in paragraph 188 set forth conclusions of law for which no response is required.

189. Monsanto lacks information or knowledge sufficient to form a belief as to the truth of the allegations in paragraph 189 concerning the plaintiff’s claimed use of Roundup®-branded products and therefore denies those allegations. The remaining allegations in paragraph 189 set forth conclusions of law for which no response is required.

190. The allegations in paragraph 190 set forth conclusions of law for which no response is required.

191. Monsanto denies the allegations in paragraph 191.

192. Monsanto lacks information or knowledge sufficient to form a belief as to the truth of the allegations in paragraph 192 and therefore denies those allegations.

193. Monsanto lacks information or knowledge sufficient to form a belief as to the truth of the allegations in paragraph 193 concerning the condition of any Roundup®-branded product allegedly used by plaintiff or about plaintiff's alleged uses of such product and therefore denies the allegations in paragraph 193.

194. Monsanto denies the allegations in paragraph 194.

195. Monsanto denies the allegations in paragraph 195.

196. Monsanto denies the allegations in paragraph 196.

In response to the allegations in the "WHEREFORE" paragraph following paragraph 196, Monsanto demands that judgment be entered in its favor and against plaintiff; that plaintiff's Complaint be dismissed, with prejudice; and that Monsanto be awarded costs of suit and reasonable attorney's fees as allowed by law and such further and additional relief as this Court may deem just and proper.

In response to the allegations in the section entitled "PRAYER FOR RELIEF," Monsanto denies that plaintiff is entitled to the relief sought therein, including any judgment for any damages, interest, costs, or any other relief whatsoever.

Every allegation in the Complaint that is not specifically and expressly admitted in this Answer is hereby specifically and expressly denied.

SEPARATE AND AFFIRMATIVE DEFENSES

1. The Complaint, in whole or part, fails to state a claim or cause of action against Monsanto upon which relief can be granted.

2. Plaintiff's claims are barred because plaintiff cannot proffer any scientifically reliable evidence that the products at issue were defective or unreasonably dangerous.

3. Any alleged negligent or culpable conduct of Monsanto, none being admitted, was so insubstantial as to be insufficient to be a proximate or substantial contributing cause of plaintiff's alleged injuries.

4. Plaintiff's claims are barred, in whole or in part, because the products at issue were designed, manufactured, marketed and labeled with proper warnings, information, cautions and instructions, in accordance with the state of the art and the state of scientific and technological knowledge.

5. Plaintiff's claims are barred, in whole or in part, because the products at issue were not defective or unreasonably dangerous in that they complied with, at all relevant times, all applicable government safety standards.

6. Any claims based on allegations that Monsanto misled, defrauded, made misrepresentations to, or withheld information from U.S. EPA are preempted by federal law. *See, e.g., Buckman Co. v. Plaintiffs' Legal Comm.*, 531 U.S. 341 (2001); *Nathan Kimmel, Inc. v. Dowelanco*, 275 F.3d 1199 (9th Cir. 2002).

7. Plaintiff's claims are preempted, in whole or in part, by applicable federal law relating to the design, testing, producing, manufacturing, labeling, distributing, modeling, processing, and supply of Roundup®-branded products and/or glyphosate-containing products.

8. Plaintiff's claims are preempted, in whole or in part, because of U.S. EPA findings that glyphosate does not cause cancer in humans and/or because of U.S. EPA-approved product labeling.

9. Plaintiff's claims are barred, in whole or in part, by the doctrine of primary jurisdiction, including by the authority delegated by Congress to the U.S. EPA.

10. Plaintiff's claims are barred, in whole or in part, because plaintiff's injuries, if any, were the result of conduct of plaintiff, independent third parties, and/or events that were extraordinary under the circumstances, not foreseeable in the normal course of events, and/or independent, intervening and superseding causes of the alleged injuries, including but not limited to plaintiff's pre-existing medical conditions.

11. The doctrines contained in Restatement (Second) of Torts § 402A, comments j and k, bar plaintiff's claims against Monsanto in whole or in part.

12. Applicable statutes of limitations and/or repose bar plaintiff's claims in whole or in part.

13. Plaintiff's misuse or abnormal use of the product or failure to follow instructions bar plaintiff's claims in whole or in part.

14. If plaintiff suffered injuries or damages as alleged, which is denied, such injuries or damages resulted from: (a) acts or omissions of persons or entities for which Monsanto is neither liable nor responsible or, in the alternative, Monsanto is entitled to an assessment of the relative degree of fault of all such persons and entities; or (b) resulted from diseases and/or causes that are not related or connected with any product sold, distributed, or manufactured by Monsanto. Such acts or omissions on the part of others or diseases or causes constitute an independent, intervening and sole proximate cause of plaintiff's alleged injuries or damages.

15. Monsanto had no legal relationship or privity with plaintiff and owed no duty to plaintiff by which liability could be attributed to it.

16. Monsanto made no warranties of any kind or any representations of any nature whatsoever to plaintiff. If any such warranties were made, which Monsanto specifically denies, then plaintiff failed to give notice of any breach thereof.

17. Plaintiff's claims are preempted in whole or part by the Freedom of Speech Clause of the First Amendment of the U.S. Constitution.

18. Plaintiff's claims for punitive and/or exemplary damages are barred because such an award would violate Monsanto's due process, equal protection and other rights under the United States Constitution, the Pennsylvania Constitution, and/or other applicable state constitutions.

19. Plaintiff's claims for punitive and/or exemplary damages are barred because plaintiff has failed to allege conduct warranting imposition of punitive damages under Pennsylvania law and/or other applicable state laws.

20. Plaintiff's claims for punitive and/or exemplary damages are barred and/or limited by operation of state and/or federal law.

21. Plaintiff's claims are barred in whole or in part by plaintiff's own contributory/comparative negligence.

22. Plaintiff's claims are barred in whole or in part by plaintiff's own failure to mitigate damages.

23. Plaintiff's claims are barred in whole or in part by the sophisticated user doctrine.

24. To the extent that plaintiff recovered payments for her alleged injuries from any collateral source(s) or other source(s), plaintiff's recovery in this lawsuit, if any, shall be reduced to the extent allowed by applicable law.

25. If plaintiff has been injured or damaged, no injury or damages being admitted, such injuries were not caused by a Monsanto product.

26. Plaintiff's claims are barred to the extent that plaintiff seeks relief under the laws of states that do not govern plaintiff's claims.

27. Plaintiff's claims are barred or limited to the extent that plaintiff asserts claims that are governed by the laws of a state that does not recognize or limit such claims.

28. Monsanto hereby preserves any and all defenses under *Tincher v. Omega Flex, Inc.*, 104 A.3d 328 (Pa. 2014).

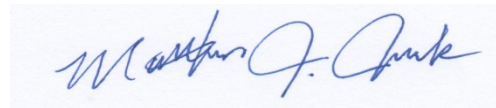
29. Monsanto hereby gives notice that it intends to rely upon such other defenses as may become available or apparent during the course of discovery and thus reserves its right to amend this Answer to assert such defenses.

WHEREFORE, Defendant Monsanto demands judgment in its favor and against plaintiff, dismissing plaintiff's Complaint with prejudice, together with the costs of suit and such other relief as the Court deems equitable and just.

JURY TRIAL DEMAND

Monsanto demands a jury trial on all issues so triable.

Dated: May 7, 2018

A handwritten signature in blue ink, reading "Matthew J. Junk", is positioned above a horizontal line.

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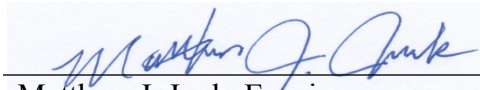
Attorneys for Defendant Monsanto Company

CERTIFICATE OF SERVICE

I certify that on this 7th day of May 2018, a copy of the foregoing Monsanto Company's Answer was filed electronically. I further certify that a true and correct copy of Monsanto Company's Answer was caused to be served upon all attorneys of record via United States mail:

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